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Alexandria, VA 22313-1450 on April 16, 2004.

INFORMATION DISCLOSURE STATEMENT Patent Application Docket No. WJS-100 Serial No. 10/626,037

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit

1614

Applicant

Warren J. Scherer

Serial No.

10/626,037

Filed

July 23, 2003

Conf. No.

1255

For

Method of Dermal Application of Brimonidine Tartrate for

Treatment of Acne Rosacea

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313

INFORMATION DISCLOSURE STATEMENT <u>UNDER 37 CFR §§1.97 AND 1.98</u>

Sir:

In accordance with 37 CFR §1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed.

It is respectfully requested that the references cited on the attached form PTO/SB/08 be considered in the examination of the subject application and that their consideration be made of record.

Applicant notes that published International Application No. PCT/EP98/00991, having International Publication No. WO 98/36730, and cited as F1 on the attached form PTO/SB/08, was written in a foreign language. However, an English language abstract is provided in the reference.

Docket No. WJS-100 Serial No. 10/626,037

Applicant respectfully requests that the reference be made of record and considered in the examination of the subject application.

Applicant respectfully asserts that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,

Frank C. Eisenschenk, Ph.D.

Patent Attorney

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Gainesville, FL 32606-6669

FCE/ssa

Attachments: Form PTO/SB/08; copies of references cited therein.

APR 2 0 2004 🕏

PTO/SB/08A (08-03) Approved for use through 07/31/2006. OMB 0651-0031

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

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of

Complete if Known			
Application Number	10/626,037		
Filing Date	July 23, 2003		
First Named Inventor	Warren J. Scherer		
Art Unit	1614		
Examiner Name			
Attorney Docket Number	WJS-100		

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. 1	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U1	US- 4,029,792	06-14-1977	Danielewicz et al.	All
	U2	US- 6,194,415 B1	02-27-2001	Wheeler et al.	All
	U3	US- 2003/0068343 A1	04-10-2003	Muizzuddin <i>et al.</i>	All
	U4	US- 4,201,211	05-06-1980	Chandrasekaran et al.	All
	U5	US- 6,534,048 B1	03-18-2003	Borgman	All
	U6	US-			
	U7	US-			
	U8	US-			
	U9	US-			

	FOREIGN PATENT DOCUMENTS					
		Foreign Patent Document	B Minner B A		Pages, Columns, Lines,	
Examiner Initials*	Cite No. ¹	Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T ⁶
	F1	WO 98/36730 A3	08-271998	Diembeck	All	
	F2					
	F3					
	F4					
	F5					
	F6					
	F7					

Examiner	Date	
Signature	Considered	

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number 10/626,037

Filling Date July 23, 2003

First Named Inventor Warren J. Scherer

Group Art Unit 1614

Examiner Name

Attorney Docket Number

of

2

NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the Examiner Cite item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue T² Initials* No. number(s), publisher, city and/or country where published. BOCKMAN, C.S., et al., "Binding and Functional Characterization of Alpha-2-Adrenergic Receptor Subtypes on Pig Vascular Endothelium," J. Pharmacol. Exp. Therapeutics, 1993, Vol. 267, pp. 1126-1133. R1 BURKE and SCHWARTZ, "Preclinical Evaluation of Brimonidine," Survey of Ophthalmology, 1996, Vol. 41 pp. S9-S18. R2 CHIEN et al., "Corneal and conjunctival/scleral penetration of p-aminoclonidine, AGN 190342, and clonidine in rabbit eyes," Current Eye Research, 1990, Vol. 9, No. 11, pp. 1051-1059. R3 CHOTANI et al., "Silent α_{2C}-adrenergic receptors enable cold-induced vasoconstriction in cutaneous arteries." Am. J. Physiol. Heart Circ. Physiol., 2000, Vol. 278, pp. H1075-H1083. R4 FREEDMAN and BLACKER, "Estrogen raises the sweating threshold in postmenopausal women with hot flashes," Fertility and Sterility, 2002, Vol. 77, No. 3, pp. 487-490. R5 GUARRERA et al., "Flushing in Rosacea: A Possible Mechanism," Arch. Dermatol. Res., 1982, Vol. 272 pp. 311-R6 NAKAMURA and FERREIRA, "Peripheral analgesic action of clonidine: mediation by release of endogenous enkephalin-like substances," European Journal of Pharmacology, 1988, Vol.146, pp. 223-228, R7 NIELSEN et al., "Postjunctional α2-adrenoceptors mediate vasoconstriction in human subcutaneous resistance vessels," Br. J. Pharmacol., 1989, Vol. 97, pp. 829-834. R8 WALTERS, "Development and Use of Brimonidine in Treating Acute and Chronic Elevations of Intraocular Pressure: A Review of Safety, Efficacy, Dose Response, and Dosing Studies," Survey of Ophthalmology, 1996, R9 Vol. 41, pp. S19-S26. WILKIN, "Why is flushing limited to a mostly facial cutaneous distribution?" J. Am. Acad. Dermatol., 1988, Vol. 19, pp. 309-313. R10 WILKIN, "Effect of Subdepressor Clonidine on Flushing Reactions in Rosacea," Arch. Dermatol., 1983, Vol. 119. pp. 211-214. **R11** BURKE and SCHWARTZ, "Preclinical Evaluation of Brimonidine," Survey of Ophthalmology, 1996, Vol. 41 pp. S9-S18. R12 **R13**

Examiner Date Signature Considered

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